

SECTION
2E

Outpatient dialysis services

R E C O M M E N D A T I O N

The Congress should update the composite rate by the projected rate of increase in the end-stage renal disease market basket index less 0.4 percent for calendar year 2006.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

SECTION 2E

Section 2E: Outpatient dialysis services

Although the MMA mandates substantial changes to outpatient dialysis payment policy in 2005, the law specifically does not call for broadening the payment bundle, a necessary component for modernizing this payment system. Further, freestanding and hospital-based facilities will continue to be paid differently for providing the same services, which could lead to financial incentives inappropriately affecting decisions about where care is provided.

Notwithstanding the changes to payment policy, most of our indicators of payment adequacy in 2005 are positive. Beneficiaries' access to care is good, providers' capacity is increasing, quality is improving for some measures, and providers' access to capital is good. Nevertheless, we project the Medicare margin for composite rate services and injectable drugs will decline from 4.2 percent in 2003 to about 0 percent in 2005. Because we are concerned about the trend in the Medicare margin and the uncertainty in payments due to recent changes in law and regulation, the Congress should update the composite rate by the projected rate of increase in the end-stage renal disease market basket index less 0.4 percent for calendar year 2006.

In this section

- The ESRD population is growing, and spending is increasing
- The outpatient dialysis payment system will change in 2005
- Are Medicare payments adequate in 2005?
- How should Medicare payments change in 2006?

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. Occurring at the last stage of progressive impairment of kidney function, the illness is caused by a number of conditions, including diabetes, hypertension, glomerulonephritis, and cystic kidney disease. Individuals with ESRD require either chronic dialysis or a kidney transplant to stay alive. The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD, and about 300,000 patients were enrolled in 2002.¹

Until the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was passed, Medicare's payment system for outpatient dialysis services remained essentially the same since it was first implemented in 1983. The MMA changes outpatient dialysis payment policies by:

- shifting some of the profits previously associated with payments for separately billable drugs to the prospective payment rate for outpatient dialysis services (the composite rate),
- adjusting the composite rate by case mix, and
- paying acquisition cost for most separately billable injectable drugs.

The Commission reviewed the changes mandated by the MMA against Medicare's payment policy objectives, which include providing cost-effective, quality care to patients using the most suitable modality in the most suitable setting; promoting access to services; and giving dialysis providers incentives to control costs.

The MMA improves payment for dialysis in some respects but falls short of MedPAC's recommendations for modernizing the outpatient dialysis payment system. The MMA does not bundle composite rate services and injectable drugs together, a necessary component for modernizing this payment system. In addition, freestanding and hospital-based facilities continue to be paid differently for providing the same services—composite rate services and injectable drugs—which could lead to financial incentives inappropriately affecting decisions about where care is provided. Finally, the MMA does not strengthen efforts to improve dialysis quality.

Consequently, MedPAC reiterates its recommendation to expand the prospective payment bundle and include dialysis injectables as well as other services that providers

can bill separately (MedPAC 2001). The Commission also raises concerns about how the MMA changes payment for composite rate services and injectable drugs. We expect to continue to explore these issues in the coming months.

In the second section of this chapter, we address the two questions posed by our update framework: whether Medicare's payments for dialysis services are adequate in 2005 and whether Medicare's payments should change for calendar year 2006. Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, volume of services, quality, and access to capital. Even so, the Medicare margin for composite rate services and injectable drugs declined from 4.2 percent in 2003 to 0 (-0.03) percent in 2005. Because we are concerned about the trend in the Medicare margin and the uncertainty in payments due to recent changes in law and regulation, the Congress should update the composite rate by the projected rate of increase in the ESRD market basket index less 0.4 percent for 2006. Currently, the index projects that providers' costs will increase by 2.9 percent between 2005 and 2006.

The ESRD population is growing, and spending is increasing

Between 1993 and 2002, the number of ESRD patients grew by about 6.3 percent per year (Table 2E-1). Similarly, the number of dialysis patients grew by 6.1 percent per year during this period. Nearly three-quarters of all ESRD patients undergo dialysis because there are a limited number of kidneys available for transplants.

Why did the number of ESRD patients grow between 1993 and 2002? The growth is linked to the aging of the U.S. population as well as to an increase in the number of people with diabetes, a disease that is both a risk factor for ESRD and the most frequent underlying cause of ESRD (Table 2E-2, p. 124). Factors that increase a person's risk of diabetes include older age, lack of exercise, and a family history of the disease; however, being overweight or obese is the single most important predictor.

Although most ESRD patients (93 percent) are eligible for Medicare, not all are insured by Medicare as the primary payer. Medicare is the secondary payer for patients who are insured under employer group health plans when they

**TABLE
2E-1****The ESRD population is growing, and most patients undergo dialysis**

	1993		1997		2002	
	Patients (thousands)	Percent	Patients (thousands)	Percent	Patients (thousands)	Percent
Total	248.2	100%	334.3	100%	431.3	100%
Dialysis	180.9	73	244.2	73	308.9	72
In-center hemodialysis	149.1	60	210.0	63	280.4	65
Home hemodialysis	0.8	<1	1.7	1	1.2	<1
Peritoneal dialysis	27.3	11	28.6	9	24.9	6
Unknown	3.7	2	3.9	1	2.4	1
Functioning graft and kidney transplant	67.4	27	90.1	27	122.4	28

Note: ESRD (end-stage renal disease). Totals may not equal sum of the components due to rounding.

Source: Compiled by MedPAC from the United States Renal Data System.

develop ESRD. The Balanced Budget Act of 1997 extended the period for which these plans are the primary payer from 18 to 30 months.

Freestanding facilities currently provide the majority of dialysis services, accounting for 84 percent of all facilities and 87 percent of treatments. Medicare spending for outpatient dialysis services provided by freestanding dialysis facilities totaled about \$6.0 billion in 2003. Of this total, payments for composite rate services accounted for 59 percent of all Medicare spending, while payments for injectable drugs comprised 41 percent of spending. (By contrast, payments for injectable drugs comprised about 30 percent of spending in 1996.) On a per-treatment basis, the payment for composite rate services and dialysis injectables averaged \$130 and \$89, respectively, in 2003. Separate payments for medical supplies, laboratory services, and blood products accounted for less than 1 percent of payments for freestanding facilities in 2003.

Total Medicare spending for composite rate services and injectable drugs provided by freestanding facilities increased by 10 percent per year between 1996 and 2003.² Two factors that contribute to the growth in Medicare spending are the increasing size of the ESRD population (mentioned earlier) and the diffusion of new technologies—primarily drugs and biologics. Dialysis injectable drugs such as erythropoietin, iron supplements,

and vitamin D analogues were not available when the outpatient dialysis payment system was implemented in 1983. Between 1996 and 2003, spending increased by 14 percent per year for erythropoietin and 17 percent per year for other injectable drugs.

The outpatient dialysis payment system will change in 2005

The MMA's changes reflect concerns about how Medicare paid for outpatient dialysis services. The law changes the payment system by:

- paying the acquisition cost for most injectable drugs,
- paying an add-on adjustment to the composite rate that represents the difference between Medicare's payments and providers' acquisition costs for injectable drugs (i.e., the profit margin), and
- adjusting both the composite rate and the add-on adjustment by a limited set of case-mix variables.

In addition to these changes, the law updates the composite rate by 1.6 percent in 2005. Table 2E-3 (p. 125) summarizes the pre- and post-MMA outpatient dialysis payment system.

**TABLE
2E-2**

Diabetics and the elderly are the fastest growing segments of the ESRD population

	Percent of total in 2002	Annual percent change 1996–2002
Total (n = 431,284)	100%	6%
Age		
0–19	2	3
20–44	21	2
45–64	42	7
65–74	20	5
75+	15	8
Sex		
Male	55	6
Female	45	5
Race/Ethnicity		
White	62	5
African American	31	5
Native American	1	5
Other	6	10
Underlying cause of ESRD		
Diabetes	36	8
Hypertension	24	5
Glomerulonephritis	16	4
Other causes	25	4

Note: ESRD (end-stage renal disease). Totals may not equal sum of the components due to rounding.

Source: Compiled by MedPAC from the United States Renal Data System.

The MMA does not, however, change the basic structure of the dialysis payment system—separate payment for dialysis treatments and injectable drugs. Providers will continue to be paid the composite rate for each dialysis treatment provided in dialysis facilities (in-center) or in patients’ homes.³ In 2005 the base composite rate for hospital-based facilities will be \$132—on average \$4 more than for freestanding facilities. This difference stems from the Omnibus Budget Reconciliation Act of 1981, by which the Congress mandated separate rates for the two types of facilities.

Post-MMA changes to the composite rate

In 2005 the composite rate will change in two ways. First, facilities will be paid an add-on adjustment to the composite rate (Figure 2E-1, p. 126). This add-on adjustment is derived by moving the profit margin for the following injectable drugs to the composite rate payment:

- erythropoietin and all other separately billable injectable drugs provided by freestanding facilities, which CMS estimates to be \$385 million in 2005, and
- erythropoietin provided by hospital-based facilities, which CMS estimates to be \$5 million in 2005.

For both freestanding and hospital-based facilities, the add-on adjustment will be 8.7 percent of their composite rate. Implementing a single add-on adjustment results in transferring dollars from freestanding to hospital-based facilities, estimated at \$1.41 per treatment by CMS or \$38.8 million based on an estimated 27.5 million treatments freestanding dialysis facilities will provide in 2005.

Second, the composite rate and the add-on adjustment will be adjusted for case mix.⁴ The case-mix measures that will be used beginning in April 2005 are:

- age (<18, 18–44, 45–59, 60–69, 70–79, ≥80 years) and
- two body measurement variables—body surface area and body mass index—calculated from patients’ height and weight when they develop ESRD. Dialysis facilities will be required to update patients’ height and weight on dialysis claims beginning in January 2005.⁵

Post-MMA changes to payment for injectable drugs

Under the MMA, facilities will be paid their acquisition cost for most injectable drugs. Beginning in January 2005, freestanding facilities will be paid an average acquisition payment (AAP) for the top 10 injectable drugs that they can bill separately. These 10 drugs—erythropoietin, calcitriol, doxercalciferol, iron dextran, iron sucrose, levocarnitine, paricalcitol, sodium ferric glut, alteplase recombinant, and vancomycin—accounted for 98 percent of all drug spending by freestanding facilities in 2003. CMS will derive the AAPs for these drugs from the first of two studies by the Office of Inspector General (OIG) (OIG

**TABLE
2E-3**

Payment policies for outpatient dialysis will change in 2005

Payment policy for type of service	Freestanding facilities		Hospital-based facilities	
	Pre-MMA 2004	Post-MMA 2005	Pre-MMA 2004	Post-MMA 2005
Composite rate				
Update	None	1.6%	None	1.6%
Add-on adjustment	N/A	8.7 % of the composite rate	N/A	8.7 % of the composite rate
Case-mix adjuster	None	6 age groups; 2 measures of body mass	None	6 age groups; 2 measures of body mass
Injectable drugs	\$10 per 1,000 units for EPO; 95% AWP for all other drugs	AAP for top 10 drugs; ASP+6% for all other drugs	\$10 per 1,000 units for EPO; reasonable cost for all other drugs	AAP for EPO; reasonable cost for all other drugs

Note: MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003), N/A (not applicable), AAP (average acquisition payment), EPO (erythropoietin), AWP (average wholesale price), ASP (average sales price). The composite rate includes all nursing services, supplies, equipment, and selected drugs associated with a single dialysis treatment. The add-on adjustment represents the difference between Medicare's payments and providers' acquisition costs for separately billable injectable drugs.

Source: Medicare program; revisions to payment policies under the physician fee schedule for calendar year 2005; final rule. Federal Register, November 15, 2004, Vol. 69, No. 219, p. 66235.

2004).⁶ To set the 2005 payment rates, CMS will update the 2003 values of average acquisition costs reported by the OIG using the Producer Price Index. For all other separately billable drugs, including those launched in 2006 and beyond, freestanding facilities will be paid the average sales price (ASP) plus 6 percent. CMS will use the same data on ASP that is used to pay for Part B drugs provided by non-ESRD providers.

The 2005 payment rate for these 10 drugs, on a per-unit basis, is less than the 2004 payment rate. Payment per unit declines the least for erythropoietin (by 2 percent, from \$10 to \$9.76) and the most for levocarnitine (by 61 percent, from \$35.23 to \$13.63) (CMS 2004b). In addition to the changes in per-unit payment, CMS will pay facilities 50 cents per erythropoietin administration to cover the cost of syringes they use. Under pre-MMA policies, the cost of syringes was included in the payment rate for erythropoietin. This change in policy makes payment for erythropoietin consistent with how CMS covers the cost of syringes used for other dialysis

injectables. The 50 cent payment per administration to cover the cost of syringes for other injectable drugs remains unchanged post-MMA.

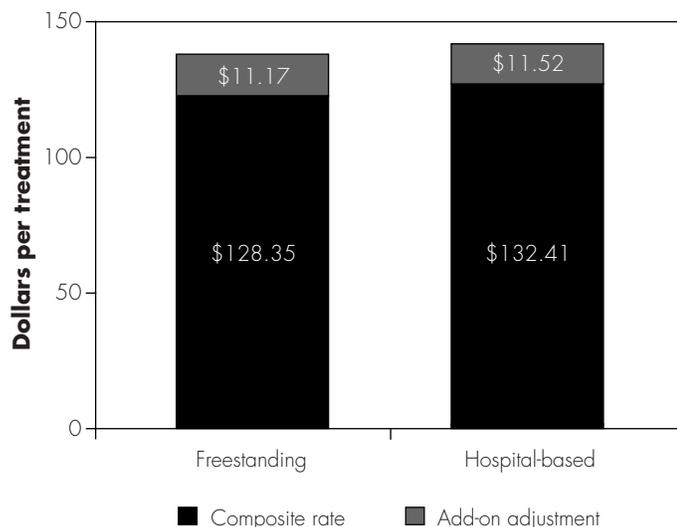
Hospital-based facilities also will be paid AAP for erythropoietin. But payment for all other drugs remains unchanged; hospital-based facilities will continue to be paid reasonable cost.

How will the MMA affect dialysis providers?

CMS projects that in 2005 aggregate payments for composite rate services and injectable drugs will increase by 1.0 percent for all facilities (Table 2E-4, p. 126). This overall change reflects the 1.6 percent update to the composite rate, the changes in drug payment, and case-mix adjustment. Overall payments will increase by 1.0 percent because the 1.6 percent update applies only to composite rate payments, which the agency estimates will account for 60 percent of aggregate payments. The MMA mandated that all of the other changes to payment policy be budget neutral.

**FIGURE
2E-1**

**The add-on adjustment is
8.7 percent of
the composite rate**



Note: The composite rate includes all nursing, supplies, equipment, and selected drugs associated with a single dialysis treatment. The add-on adjustment represents the difference between Medicare's payments and providers' acquisition costs for separately billable injectable drugs. These payment rates do not reflect the budget-neutral adjustment of 0.9116 that will be applied to the sum of the composite rate and the add-on adjustment.

Source: Medicare program; revisions to payment policies under the physician fee schedule for calendar year 2005; final rule. Federal Register, November 15, 2004, Vol. 69, No. 219, p. 66235.

The impact on particular types of facilities varies. For example, overall payments for freestanding facilities will increase by 0.4 percent, while payments for hospital-based facilities will increase by 6.6 percent. As mentioned earlier, this difference comes from the single add-on adjustment, which distributes a portion of the margin associated with the injectable drugs from freestanding to hospital-based facilities. Payments to nonprofit facilities are projected to increase more than those to for-profit facilities because most freestanding facilities are for profit. The change will affect rural and urban facilities similarly because the proportion of freestanding facilities in rural and urban areas is similar (80 percent versus 87 percent, respectively, based on MedPAC analysis of facility survey data). CMS projects payments will vary based on the size of the facility.

Issues concerning the post-MMA outpatient dialysis payment system

The changes mandated by the MMA fall short of MedPAC's previous recommendations for modernizing the outpatient dialysis payment system. Medicare's policies did not appropriately pay for outpatient dialysis services because neither payments for services in the payment bundle nor payments for certain services outside the payment bundle accurately reflected facilities' expected costs pre-MMA. Injectable drug spending has increased significantly since the mid-1990s, and the profitability of these services offset the decreasing payment margins under the composite rate. Therefore, in March 2001 and again in October 2003, MedPAC recommended that the outpatient dialysis payment system be modernized so that Medicare could better achieve its objectives of providing incentives for controlling costs and promoting access to quality services. It remains to be seen how providers' incentives will change post-MMA.

**TABLE
2E-4**

CMS projects that outpatient dialysis payments will change in 2005

Type of facility	Effect of changes in drug payments	Overall effect
All	0.0%	1.0%
Urban	0.0	0.9
Rural	-0.1	1.1
For profit	-0.7	0.1
Nonprofit	3.0	4.3
Freestanding	-0.6	0.4
Hospital based	5.2	6.6
Small (< 5,000 treatments per year)	0.2	1.5
Medium (5,000-10,000 per year)	-0.3	0.7
Large (> 10,000 treatments per year)	0.2	1.0

Note: The second column shows the projected impact of the drug payment policies implemented in 2005 on aggregate payments for dialysis providers, including changes in payment for injectable drugs and the add-on adjustment. The last column shows the projected impact of all changes in dialysis payment policies implemented in 2005 on aggregate payments for dialysis providers, including the composite rate update, the add-on adjustment, the budget-neutrality adjustment, and the case-mix adjustments.

Source: Medicare program; revisions to payment policies under the physician fee schedule for calendar year 2005; final rule. Federal Register, November 15, 2004, Vol. 69, No. 219, p. 66235.

Not only will separate payment for composite rate services and injectable drugs continue in 2005, but the post-MMA payment system will be more complex because of the add-on adjustment to the composite rate. Further, the MMA does not strengthen efforts to improve quality. Under the MMA, payment will not be linked to the quality of care physicians and facilities treating dialysis patients provide. The law, however, does begin to consider expanding the payment bundle. Beginning on January 1, 2006, the Secretary must conduct a three-year demonstration to test a broader payment bundle that includes injectable drugs and clinical laboratory tests that are currently excluded from it.

Because the MMA's changes fall short of MedPAC's approach to modernize the payment system, we reiterate our March 2001 recommendations to:

- Expand the payment bundle to include widely used injectable drugs and laboratory services that are currently excluded from it. The Secretary should also consider including other services needed by ESRD patients, such as vascular access monitoring services, nutritional management, and Medicare-covered preventive services.
- Consider whether the unit of payment—a single dialysis session—should be revised. Changing the unit of payment to either a week or a month might give providers more flexibility in providing care and better enable Medicare to include services in the broader bundle that are not always provided during each session.
- Adjust payments for method, dose, and frequency of dialysis, and patient case mix (which is mandated by the MMA for composite rate services). Doing so will better match payments to efficient providers' costs and will reduce the incentive that providers may have to select less costly patients.
- Adjust the payment rate using a current wage index based on occupations typically used in providing dialysis.

Along with modernizing the payment system, efforts to measure and report on dialysis quality to ensure provider accountability need to be expanded. In March 2000 we recommended that CMS collect information on ESRD patients' satisfaction with the quality of, and their access to, care (MedPAC 2000). In March 2004 we

recommended linking payment to quality for physicians and facilities providing outpatient dialysis services (MedPAC 2004). By modernizing the outpatient dialysis payment system, Medicare can better achieve its objective of controlling costs and promoting access to quality services.

In the next three sections, we raise key issues concerning the post-MMA outpatient dialysis payment system. These issues include payment for composite rate services, payment for injectable drugs, and efforts to improve dialysis quality. The Commission expects to explore these issues in the coming months.

Issues concerning the composite rate post-MMA

The changes mandated by the MMA raise two issues concerning payment for composite rate services. The first is that freestanding and hospital-based facilities will continue to be paid differently for composite rate services. Hospital-based facilities will continue to be paid, on average, \$4 more for composite rate services than freestanding facilities. The 1983 rule implementing the composite rate attributed this \$4 difference to overhead, not patient complexity or case mix.

MedPAC is also concerned that the add-on adjustment increases the complexity of the payment system. This methodology may not be the most appropriate way to pay for dialysis services. MedPAC and other researchers have noted that the pre-MMA drug payment policy promoted a less-than-efficient use of drugs by certain providers. The add-on adjustment continues to base payment on this policy. Another issue is whether the composite rate and add-on adjustment together is the appropriate level of payment for a dialysis treatment. Dialysis care has changed since 1983, but the composite rate has never been re-based. Like other payment bundles, new technologies have replaced older ones, and services are now included in the bundle that were not available when the payment system was first implemented.

Issues concerning payment for separately billable drugs post-MMA

The changes mandated by the MMA raise two issues concerning payment for injectable drugs. The first is that not all drugs will be paid at acquisition cost. For drugs other than erythropoietin, hospital-based facilities will be paid reasonable cost, which may not necessarily be equal

to acquisition cost. Rather, reasonable cost reflects the charges, including overhead, set by the hospital, reduced to costs using a cost-to-charge ratio. The resulting cost may thus reflect the hospital's charging and accounting practices.

The second issue concerns deriving payment rates in 2006 and beyond from the data on acquisition cost obtained from the OIG. The concerns surrounding this data source include:

- It may not accurately reflect providers' acquisition costs in 2006 and beyond if changes occur in the negotiating practices between manufacturers and providers.
- It does not provide information on all injectable drugs currently used by providers.
- It does not provide information on the prices paid by hospital-based facilities.
- It will only be updated once to include the prices of drugs that did not have a billing code before 2004.

Ideally, the data source that Medicare uses to obtain providers' acquisition cost should provide cost data on all drugs, be regularly updated to include the cost of new drugs, and accurately reflect providers' acquisition costs.

Improving the quality of dialysis care

CMS has strived to improve dialysis quality through a variety of approaches, including monitoring and reporting on quality and sponsoring quality improvement activities.

Together, these efforts attempt to hold providers accountable for the care they give to beneficiaries. Last year, MedPAC recommended that the Congress implement a payment policy incorporating quality incentives for physicians and facilities providing outpatient dialysis services.

Since 1993, CMS has monitored and reported on key aspects of the dialysis process—including anemia and nutrition levels, dialysis adequacy, and, most recently, vascular access management—in its annual survey of dialysis patients. The agency should continue to update these measures over time. For example, CMS has not yet included bone disease as a clinical performance measure even though the National Kidney Foundation (NKF) recently released a clinical guideline on this topic.

The agency's quality improvement efforts encourage providers to assess their performances, make changes, reassess quality, and strive for continuous improvements. The 18 ESRD network organizations have assisted the agency in developing and implementing these activities. Most recently, CMS and the network organizations have collaborated to improve vascular care. This effort, "Fistula First," is a nationwide initiative to increase the use of arteriovenous fistulas, a type of vascular access that is associated with improved patient outcomes compared with other types of vascular access.

In addition to these quality improvement activities, CMS reports facility-specific information on its Dialysis Facility Compare website, thus promoting more active consumer participation in health decisions. For each Medicare-certified facility, the website reports the types of dialysis services available and measures of dialysis adequacy, anemia status, and mortality.

It will be critical for the Secretary to continue current efforts to monitor and improve the quality of dialysis care. The three payment methods used to pay for injectable drugs introduce a new set of incentives in 2005. To the extent that a given method results in over- or underpayment, providers may have an incentive to stint on care or to substitute one drug for another. Of concern is whether the substituted drug results in a lower therapeutic effect than originally attained. In addition, the changes in 2005 may introduce a new set of incentives for providers to refuse to care for patients who are sicker or more complex on average than other patients.

MedPAC's future workplan

MedPAC's future workplan stresses monitoring access to care in 2005 and beyond and reassessing the overall design of the outpatient dialysis payment system.

Monitoring beneficiaries' access to care is critical to assessing the effect of the changes that CMS will implement in 2005. Facilities that are no longer profitable could close. Shifts in care could result if providers find that providing certain services is no longer profitable. Different approaches that the Commission may use to monitor beneficiaries' access to care include measuring changes in:

- The number of facilities and their capacity to provide care in rural and urban areas and by Zip code. Comparing closures of facilities to openings in a given area is one indicator of beneficiaries' access to care.

- The distance patients have to travel to obtain care. Travel time might increase for beneficiaries whose dialysis facilities close. Some researchers have linked longer travel time to poorer compliance with dialysis treatments.
- Rates of hospitalization. Patients who are underdialyzed and patients suffering from anemia are more likely to be hospitalized. Thus, an increase in hospitalization rates could suggest that patients may not be obtaining needed care.
- Use of services and sites of care. If providers find that certain services are no longer profitable, patients may have to seek care from other provider types. Thus, it will be important to monitor beneficiaries' use and site of care.

In addition to monitoring beneficiaries' access to care, the Commission plans to continue assessing different aspects of the outpatient dialysis payment system's design, including using a more current wage index, analyzing what services should be included in a broader bundle, and examining factors that affect providers' costs in providing a broader bundle.

- CMS chose not to update the wage index of the composite rate even though the MMA gave the agency the authority to do so.⁷ MedPAC plans to analyze the effect of using more recent wage indexes.
- Candidates for an expanded bundle include widely used injectable drugs and laboratory services that are currently excluded from it. Including other services needed by most dialysis patients, like vascular access monitoring services and Medicare-covered preventive services, might control total spending and lower the high level of morbidity among this population.
- Adjusting for case mix and other factors affecting costs will be critical with an expanded bundle. Our June 2003 analysis showed that aggregate costs for composite rate services and injectable drugs vary widely, suggesting that some of the differences in facilities' costs may be explained by the health status of their patients.

Are Medicare payments adequate in 2005?

The first question in applying MedPAC's approach for updating payments is whether the current level of Medicare's payments for outpatient dialysis services is adequate. The Commission answers this question by looking at aggregate costs for composite rate services and dialysis injectables. We include the payments and costs for injectable medications because their use has increased significantly throughout the 1990s and their effect on the financial performance of facilities is significant. Including payments and costs for dialysis injectables gives a more accurate picture of the financial performance of dialysis providers and the adequacy of Medicare's payments for dialysis services.

Most of our indicators of payment adequacy are positive. Beneficiaries are not facing systematic problems in accessing care, providers have sufficient capacity to meet demand and the number of facilities—particularly for-profit facilities—continues to increase, the volume of services is increasing, quality is improving for some measures, and providers' access to capital is good. Still, we project the Medicare margin for composite rate services and injectable drugs will fall from 4.2 percent in 2003 to 0 (–0.03) percent in 2005. The projected decline between 2003 and 2005 results from the composite rate not being increased in 2004 and the impact of the new changes in law and regulation implemented in 2005.

Beneficiaries' access to care

A review of the published literature shows no evidence of beneficiaries facing systematic problems in obtaining necessary dialysis care in 2003 and 2004. Reports of facility closings tend to be linked to local issues, such as rising real estate prices in certain areas, shortages of technicians and nurses, and states' certificate-of-need regulations.

Access to specific types of dialysis—in-center hemodialysis, peritoneal dialysis, and home hemodialysis—shows little change over time. Between 1998 and 2004, at least 96 percent of all facilities offered in-center hemodialysis and 45 percent offered some type of peritoneal dialysis.

Our analysis of the pattern of facility closure suggests that beneficiaries should not be having systematic problems obtaining care in rural areas, health professional shortage

areas, and lower-income areas. Facilities that closed in 2004 were as likely to be rural, health professional shortage, and lower-income areas as those that remained in business between 2003 and 2004.

But closures may be disproportionately occurring in areas where a higher proportion of the population is African American: 18 percent of the population were African American in areas served by facilities that remained open versus 24 percent in areas where facilities closed. The variables measuring income, race, and ethnicity are derived from area-level (ecologic) data. Area-level data cannot provide direct information about the causality of a relationship; rather, only information on potential associations can be identified. We will continue to monitor any changes in access and quality by beneficiaries' demographic and socioeconomic characteristics.

Finally, there is no data yet about how satisfied beneficiaries are with the care outpatient dialysis facilities provide. In March 2000, MedPAC recommended that CMS collect information on ESRD patients' satisfaction with the quality of, and their access to, care (MedPAC 2000). CMS and the Agency for Health Care Research and Quality started to develop a consumer assessment survey for care delivered in renal dialysis facilities in 2002. Once completed, this survey will be a part of the other Consumer Assessment of Health Plans surveys, some of which MedPAC uses to assess access to care in other sectors, including home health.

Changes in the supply of providers

Providers' capacity to deliver care increased steadily between 1993 and 2003 (Table 2E-5). The number of facilities, in-center hemodialysis stations, and patients all increased at a similar rate:

- The number of dialysis facilities grew 7 percent annually.
- In-center hemodialysis stations grew 8 percent annually.
- In-center hemodialysis patients grew 6 percent annually.

CMS's Facility Compare database showed a net increase of 113 facilities between 2003 and 2004. Providers have kept up with the demand for dialysis by increasing the

**TABLE
2E-5**

Total number of dialysis facilities is growing; for profit and freestanding are a higher share over time

	1993	1998	2003
Total number of dialysis facilities	2,343	3,394	4,421
Mean number of hemodialysis stations	15	16	17
	Percent of all facilities		
Urban	77%	75%	75%
Rural	23	25	25
For profit	61	75	77
Nonprofit	39	25	23
Freestanding	70	79	84
Hospital based	30	21	16
Four largest chains	N/A	N/A	58
Any chain	N/A	N/A	74
Nonchain	N/A	N/A	26

Note: MSA (metropolitan statistical area) as defined by the Office of Management and Budget, N/A (not applicable).

Source: Compiled by MedPAC from the CMS facility survey file.

number of facilities, rather than increasing capacity within facilities. We based this finding on our analysis of trends in the following:

- average hemodialysis stations per facility,
- average annual in-center hemodialysis treatments per facility,
- average in-center hemodialysis treatments per dialysis station, and
- number of in-center hemodialysis shifts per week.

The total number of in-center hemodialysis treatments provided by dialysis facilities increased by about 6 percent per year from 1998 through 2003, but the average number of hemodialysis stations per facility remained relatively constant at about 17 per facility. Average total dialysis treatments per facility per year also remained relatively

constant, ranging from 9,000 to 9,400 during this period. Finally, average annual hemodialysis treatments per station remained relatively constant during this period, ranging from 617 to 623. The number of in-center hemodialysis shifts per week increased slightly, from 8.6 per week in 1998 to 10.0 in 2003; but only one-fifth of all facilities offered treatments after 5 p.m.

Opening new facilities may improve access to care by reducing the time that beneficiaries must travel to obtain care three times per week. Researchers have noted that some patients shorten their dialysis treatments or skip treatments that require longer travel times (Rocco and Burkart 1993, Sehgal et al. 1998, USRDS 1997). The sustained growth in the number of dialysis facilities, however, raises questions about the optimal efficiencies of scale and the trade-off between opening new facilities versus increasing the capacity of existing ones.

Our finding—that a greater proportion of facilities are larger, for profit, and freestanding now than in 1993—is consistent with the changes in the characteristics of dialysis providers in the 1990s. As shown in Table 2E-5, the proportion of facilities that are freestanding and for profit increased, whereas the proportion that are hospital-based or nonprofit declined. In addition, dialysis chains continue to acquire independently operated facilities. About two-thirds of all freestanding facilities were operated by the four largest for-profit chains in 2003.⁸ Our finding that freestanding and for-profit facilities have steadily increased as a share of the total throughout the 1990s suggests that dialysis facilities are sufficiently profitable to stand on their own and that providing dialysis services to ESRD patients is financially attractive to for-profit providers.

Changes in the volume of services

The number of dialysis treatments and the use of dialysis injectables continue to increase, although at different rates. Between 1993 and 2003, the rise in the number of in-center hemodialysis treatments generally kept pace with the increase in dialysis patients. The number of dialysis treatments increased, on average, by 8 percent annually; by comparison, the number of dialysis patients increased, on average, by 6 percent annually during this time.

Payments for injectable drugs increased more rapidly than payments for dialysis treatments between 1996 and 2003 (15 percent versus 7 percent per year, respectively).⁹ Consequently, revenue from injectable medications has

become increasingly important relative to revenue for composite rate services during the past eight years. In 2005 providers' incentives may change because the new drug payment policy lowers the profitability of most injectable drugs currently used. It remains to be seen whether this new policy will slow the growth in payments for injectable drugs.

The use of injectable medications has grown for several reasons. First, many of the agents—including erythropoietin and iron supplements—were only approved by the Food and Drug Administration in the late 1980s. Since their approval, the NKF has advocated their use in clinical guidelines. Many of these medications have enhanced the quality of care provided to dialysis beneficiaries. For example, the increased use of erythropoietin has reduced the proportion of dialysis patients suffering from anemia, which contributes to morbidity if not treated effectively. Medicare's coverage decisions also affect the use of these drugs. For example, CMS made a national coverage decision to cover injections of levocarnitine for patients with ESRD beginning January 1, 2003.¹⁰

Nevertheless, the profitability of certain types of injectable medications has given providers the incentive to use them. For example, prior to 2005, Medicare paid \$10 per 1,000 units for erythropoietin administered either intravenously or subcutaneously (under the skin). Paying on a per-unit basis promotes the use of the intravenous form of this medication, which requires higher average doses (more units) to achieve target hematocrit levels. Intravenous erythropoietin continues to be predominantly used despite the publication of the NKF's Dialysis Outcome Quality Initiative Clinical Practice Guideline for the treatment of anemia, which advocated subcutaneous administration.¹¹

Data from the United States Renal Data System also raise questions about the efficiency of providers in furnishing injectable drugs. Using Medicare claims data, their research shows substantial variation in spending across providers. Specifically, per-patient per-month spending varied by nearly \$200 a month for dialysis injectables across different types of providers, ranging from \$613 to \$811 (USRDS 2004). As noted later in this section, some of this variation may be related to case mix, as providers' costs vary based on patients' characteristics. Further, a previous MedPAC analysis showed no association between quality of care and providers' costs for composite

rate services, and poor outcomes for providers with higher costs for composite rate services and injectable drugs (MedPAC 2003).

Changes in quality of care

The quality of dialysis care has improved for some measures (Table 2E-6). Between 1999 and 2002, the proportion of both hemodialysis and peritoneal patients receiving inadequate dialysis and having low anemia levels declined. The average length of hemodialysis sessions (an indicator of dialysis adequacy) increased slightly from 212 minutes in 1998 to 217 minutes in 2002 (CMS 1999, 2003).

No clinically important changes or improvements were found in the percentage of hemodialysis and peritoneal dialysis patients with adequate or optimal serum albumin levels in 2002 compared with those of previous years. Mean serum albumin levels below certain norms have been shown to be a marker for diminished patient survival. Some providers and researchers contend that increasing the use of certain types of medical interventions, particularly parenteral nutrition, would improve the outcomes of certain patients; however, Medicare’s coverage policies limit the number of dialysis patients who qualify for these interventions.¹²

All hemodialysis patients require vascular access—the site on the patient’s body where blood is removed and returned during dialysis. Vascular access care is another clinical area in need of substantial improvement. Use of arteriovenous (AV) fistulas, considered the best type of vascular access, increased between 1999 and 2002, from 27 percent to 33 percent of hemodialysis patients. The NKF’s clinical guideline recommends that at least 40 percent of all hemodialysis patients have an AV fistula.

Providers’ access to capital

Recent financial information and evidence about trends in the increase in dialysis facilities suggest that providers have sufficient access to capital. Providers need access to capital to improve their equipment and to open new facilities to accommodate the growing number of patients requiring dialysis. About 80 percent of all dialysis facilities are for profit, and the four largest for-profit chains account for 58 percent of all facilities and about two-thirds of freestanding facilities. These for-profit chains appear to have adequate access to capital, as demonstrated by an increase in the number of clinics, the number of patients they treat, and their earnings.

Data from industry sources suggest that both smaller and larger chains have adequate access to capital, as shown by their ability to acquire existing facilities and open new ones.¹³ Available information from reports submitted by the largest chains to the Securities and Exchange Commission shows that these chains either acquired or opened 112 facilities in 2003. In 2004, two of the largest chains announced major acquisition activities. In February 2004, the fourth largest chain announced its purchase of a smaller chain that operates 87 dialysis facilities in 15 states. In December 2004, the third largest chain announced its intent to purchase the second largest chain and that the acquisition would be financed through bonds and bank debt (Berman 2004).

Data from industry sources show that between 1999 and 2003, these chains’ net revenues grew from 7 percent to 17 percent. Key operational ratios for the largest chains suggest average or above-average performance in 2003:

- Return on equity, a key measure of capital efficiency, ranged from 18 percent to 31 percent before tax and 11 percent to 19 percent after tax.
- Return on total capital, a measure of how effectively a company uses capital, ranged from 13 percent to 30 percent.

TABLE 2E-6 Quality of dialysis care is improving for some measures

Outcome measure	1999	2000	2001	2002
Percent of in-center hemodialysis patients:				
Receiving inadequate dialysis	16%	14%	11%	11%
With low anemia levels	32	26	24	21
Who are malnourished	20	20	18	19
Dialyzed with an AV fistula	27	30	31	33
Percent of peritoneal dialysis patients:				
Receiving inadequate CAPD	32	31	32	29
Receiving inadequate CCPD	35	38	30	34
With low anemia levels	31	27	24	21
Who are malnourished	44	44	39	40

Note: AV (arteriovenous), CAPD (continuous ambulatory peritoneal dialysis), CCPD (continuous cycler-assisted peritoneal dialysis).

Source: Compiled by MedPAC from 1999–2003 Annual Reports for ESRD Clinical Performance Measures Project from CMS.

Investor analysts note that the sector benefits from recurring revenues from dialysis treatments. But they also have pointed out that dialysis providers face potential pressures from private payers and Medicare. Although about three-quarters of these chains' patients are insured by Medicare as the primary payer, the proportion of revenues from Medicare ranges from 50 percent to about 61 percent across the largest chains. Finally, the stocks of these for-profit chains have largely enjoyed positive ratings from financial analysts in 2004. Thus, these chains' stock prices have generally increased in 2004.

CMS's implementation of the MMA could affect providers' access to capital. We are continuing to monitor reports, but one investor group viewed the 2005 changes in the final rule (published in November 2004) more favorably than the proposed rule (published in August 2004); this group remains uncertain about the changes that will occur in 2006. Another recent policy that could affect providers' access to capital is CMS's proposal to revise its policy for monitoring claims for erythropoietin.¹⁴ Some investor groups viewed the proposal as "neutral to positive" for the four largest chains.

Access to capital for the largest chains may be influenced by factors other than Medicare's payments, because each chain operates other lines of business. All four chains operate clinical laboratories, and, as noted later, the revenues derived from providing laboratory services to dialysis patients—about \$10 per treatment—are not yet included in MedPAC's analysis of payments and costs.¹⁵ Two chains also manufacture dialysis equipment and supplies and provide dialysis services internationally.

Two recent events, unrelated to Medicare's payment policies, may affect access to capital for certain chains. In October 2004, three of the largest chains received subpoenas from federal prosecutors concerning laboratory testing for parathyroid hormone levels and vitamin D therapies. Another large chain agreed in September 2004 to pay \$350 million to settle claims by the Department of Justice related to Medicare and Medicaid payments and the chain's relationships with physicians and pharmaceutical companies. Although in the short term investors have not reacted negatively, we will continue to monitor the effect of these events on the chains' access to capital.

Payments and costs for 2005

Our assessment of providers' costs and the relationship between Medicare's payments and providers' costs is predicated upon: 1) whether current costs approximate what efficient providers would be expected to spend on delivering high-quality care and 2) the accuracy of the data providers include in their cost reports. In this section, we first examine three indicators of the appropriateness of current costs:

- trends in the growth in the cost per treatment for dialysis services,
- trends in the growth in the cost per treatment for dialysis injectables, and
- differences in cost per treatment for dialysis services between audited and nonaudited 2001 cost reports.

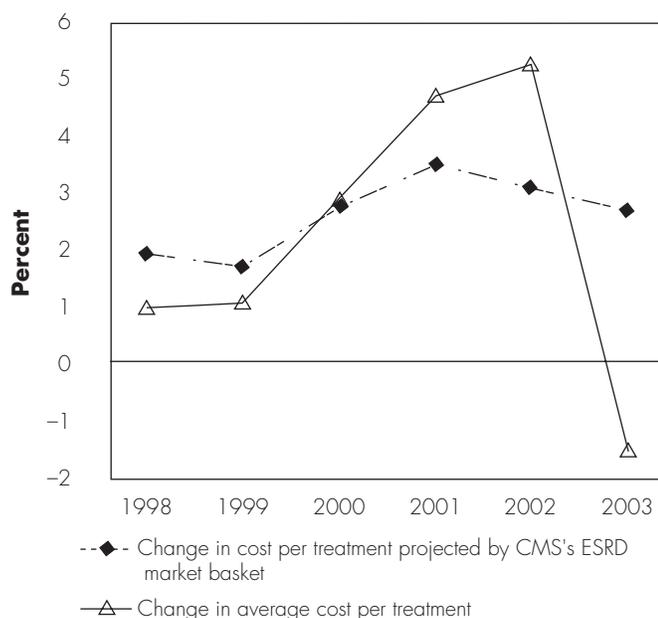
We then present our estimate of the 2003 Medicare margin for dialysis services and injectable drugs and our projection for calendar year 2005.

Average dialysis cost per treatment peaked between 2000 and 2002 and declined in 2003

Because the composite rate is predetermined, providers have an incentive to keep their costs down for these services. At issue is whether aggregate costs for composite rate services provide a reasonable representation of the costs that efficient providers would incur in providing high-quality care.

Between 1997 and 2003, three distinct trends in cost growth were apparent (Figure 2E-2, p. 134). The average cost per treatment grew modestly during the late 1990s, increasing by no more than 2 percent per year. But between 2000 and 2002, the average cost per treatment increased substantially, at 5 percent per year. Most recently—between 2002 and 2003—the average cost per treatment declined by 1.5 percent. By contrast, the ESRD market basket estimated that dialysis facilities' costs would increase by 2.5 percent between 2002 and 2003.

The recent decline in cost per treatment results from a slowdown in the growth in all but general administrative cost per treatment. In addition, certain types of providers—rural and urban facilities, for-profit facilities,

**FIGURE
2E-2****Cost growth per hemodialysis
treatment for freestanding
dialysis facilities, 1997–2003**

Note: ESRD (end-stage renal disease). Analysis of dialysis cost per treatment for freestanding dialysis facilities consistently reporting costs between 1997 and 2003.

Source: Compiled by MedPAC from the 1997–2003 cost reports from CMS.

and facilities affiliated with the four largest chains—were able to lower their cost per treatment more than others between 2002 and 2003.

Overall, the cost per in-center hemodialysis treatment for freestanding facilities increased by an average of 2.2 percent between 1997 and 2003, a rate slower than what the ESRD market basket predicted (2.6 percent). The variation in cost growth across freestanding dialysis facilities that consistently reported costs between 1997 and 2003 is worth noting. For example, per-treatment costs increased by 0.3 percent for facilities in the 25th percentile of cost growth (low cost growth), 2.0 percent for facilities in the 50th percentile, and 4.0 percent for facilities in the 75th percentile (high cost growth). A greater proportion of rural facilities had low cost growth than high cost growth (26 percent versus 18 percent, respectively), whereas a greater proportion of non-profit facilities had high cost growth than low cost growth (42 percent versus 17 percent, respectively).

**Average cost per treatment for injectable
drugs increased faster than for composite
rate services**

The cost per treatment for separately billable drugs increased by 6.2 percent between 2000 and 2003. The pre-MMA payment method for separately billable drugs gave providers no incentives to improve efficiency. It is uncertain how the change mandated by the MMA—paying acquisition cost for most drugs—will affect drug cost growth in 2005 and beyond.

The growth in erythropoietin cost per treatment was less than the growth in the cost per treatment for all other injectable drugs between 2000 and 2003 (2.5 percent versus 16.1 percent, respectively). This finding is primarily due to providers substituting new, more costly drugs for older, less expensive drugs. For example, the price of a vitamin D analogue (paricalcitol), newly approved in 1998, is twice that of the older drug it displaced (calcitriol).¹⁶ Between 2000 and 2001, Medicare spending for paricalcitol increased from \$172 million to \$386 million; by contrast, spending for calcitriol decreased from \$127 million to \$67 million.

**Audited cost reports have lower average
dialysis cost per treatment in 2001**

For dialysis providers, MedPAC has looked at the effect of using audited cost reports when examining the appropriateness of current costs. We do so because MedPAC's analysis of current costs uses only Medicare-allowable costs. For past years, MedPAC has compared 1996 audited and nonaudited cost reports and found that allowable costs as a percentage of reported costs was about 96 percent. More recently, the BBA required that each dialysis provider be audited once every three years.

We used the available portion of audited cost reports in 2001 to examine the potential effect of CMS's auditing efforts. We compared the cost per treatment calculated from audited 2001 cost reports with the cost per treatment calculated from unaudited 2001 cost reports.¹⁷ Each cost report includes an indicator reporting its status: as submitted, settled without an audit, settled with an audit, reopened.

The cost per treatment for facilities with audited cost reports differed from that of facilities whose cost reports have not been audited yet. For facilities whose cost reports were settled by an audit, the aggregate (dialysis and

injectable drugs) cost per treatment decreased from \$210 to \$203 per treatment. For facilities whose cost reports were settled without an audit, the aggregate cost per treatment remained the same using this year's and last year's 2001 cost reports. Two other important findings are worth noting:

- The audit primarily affects the dialysis cost per treatment, not the drug cost per treatment. For facilities whose cost reports were settled by an audit, the cost per treatment for composite rate services decreased by \$6 (from \$142 to \$136). By contrast, their drug cost per treatment did not change. This finding is not unexpected because the audits primarily target those cost fields that can affect Medicare payments a facility receives. The costs reported for dialysis, not drug costs, are considered when determining if Medicare will reimburse providers for bad debt.
- Dialysis cost per treatment decreased the most for general and administrative costs (13 percent) and the least for labor costs (1 percent). Capital and other direct costs decreased by about 5 percent each.

Based on these results, we determined payment margins by using the results of the 2001 audit. For facilities with audited cost reports, we calculated the ratio of allowable costs to reported costs in 2001—95.5 percent for the cost per dialysis treatment. We then applied this adjustment to the costs of composite rate services for facilities whose cost reports have not been settled yet.

The Medicare margin for freestanding dialysis facilities

For dialysis services, the Commission assesses current payments and costs by comparing Medicare's payments for composite rate services and injectable drugs with providers' Medicare-allowable costs. The most current data available on providers' costs and Medicare's payments are from 2003.

For 2003, we estimate that the aggregate Medicare margin for composite rate services and injectable drugs was 4.2 percent when the effect of the audit is considered (Table 2E-7). Aggregate margins vary based on a facility's size, affiliation with the four largest chains, and profit status. This finding stems from differences in the cost per treatment; for example, total cost per treatment was 7 percent lower for facilities affiliated with the four largest

**TABLE
2E-7**

Aggregate margins vary by type of freestanding dialysis facility, 2003

Type of facility	Aggregate margin
All facilities	4.2%
Urban	4.6
Rural	3.1
For profit	4.4
Nonprofit	0.8
Four largest chains	5.4
Other chains	0.4
Nonchain	-0.7
Furnishes per year:	
≤10,000 treatments	-0.9
>10,000 treatments	6.2

Note: Margins include payments and costs for composite rate services and injectable drugs. Margins are adjusted to reflect MedPAC's analysis of audited cost reports, which found that the ratio of allowable to reported cost per treatment for composite rate services is 95.5 percent.

Source: Compiled by MedPAC from the 2001 and 2003 cost reports and the 2003 institutional outpatient file from CMS.

chains than for facilities not affiliated with these chains. In addition, this finding also reflects differences in the proportion of payments facilities receive from composite rate services, which are less profitable than dialysis injectables.

Aggregate margins for composite rate services and injectable drugs declined from 7.6 percent in 1999 to 4.2 percent in 2003. During this period the composite rate increased twice, by 1.2 percent in 2000 and 2.4 percent in 2001. Providers' cost per treatment for composite rate services spiked between 2000 and 2002, which is discussed earlier in this section. Although providers' cost per treatment for dialysis injectables increased during this period, the difference between payments and costs remained about the same.

Between 1999 and 2003, the aggregate Medicare margin for composite rate services and injectable drugs remained positive for the majority of facilities. Among facilities that

reported cost and payment information in both 1999 and 2003, 67 percent had positive margins in both years. One-quarter of facilities had a positive margin in one year and a negative margin in the other year. Only 8 percent of facilities had negative margins in both years.

We project the Medicare margin will be 0 (–0.03) percent in 2005. This estimate reflects the net impact of the changes the MMA mandated for freestanding dialysis facilities in 2005. As mentioned earlier, although the MMA increases the composite rate payment in 2005 by 1.6 percent (which corresponds to a 1.0 percent increase in aggregate payments), CMS projects that aggregate payments will increase by 0.4 percent for freestanding dialysis facilities in 2005 after considering the other changes to outpatient dialysis payment policy. In addition, the composite rate was not increased in 2004.

Although the aggregate margin for composite rate services and injectable drugs is the most comprehensive measure we have to assess the financial performance of dialysis facilities, it does not account for the potential profitability of all services associated with outpatient dialysis. Certain dialysis-related laboratory tests are paid outside the composite rate bundle. In this case, Medicare pays the clinical laboratory, not the dialysis facility, for these laboratory services. Each of the four largest dialysis chains owns clinical laboratories, however, and those entities receive Medicare payments for dialysis-related laboratory tests. These chains reported that dialysis-related laboratory services increased their payment by about 4 percent per session.

How should Medicare payments change in 2006?

As noted earlier, MedPAC accounts for expected cost changes in the coming year primarily through the forecast of input price inflation. In 2003, CMS released its market basket index for dialysis composite rate services, as mandated by the Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act of 2000. This index projects that providers' costs will increase by 2.9 percent between 2005 and 2006.

CMS's ESRD market basket is the best available source of the change in input prices for outpatient dialysis services in the coming year (Thompson 2003). Although we previously raised questions about the agency's market basket for ESRD services, we will rely on it instead of the index developed and used by the Commission for previous updates (MedPAC 2004).

MedPAC's update framework reflects the expectation that, in the aggregate, providers should be able to reduce the quantity of inputs required to produce a unit of service while maintaining service quality. Prospective payment is designed to promote efficiency; thus productivity increases should be expected from providers. MedPAC's productivity expectation is the 10-year moving average of multifactor productivity in the economy as a whole, which is 0.8 percent.

Updating payments for composite rate services in 2006

Based on our review of the adequacy of payments for outpatient dialysis services and expected cost changes in the coming year, the Commission recommends the following:

RECOMMENDATION 2E

The Congress should update the composite rate by the projected rate of increase in the end-stage renal disease market basket index less 0.4 percent for calendar year 2006.

RATIONALE 2E

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, volume of services, quality, and access to capital. Nevertheless, the Medicare margin for composite rate services and injectable drugs declined from 7.6 percent to 4.2 percent between 1999 and 2003, and we project it will be 0 (–0.03) percent in 2005. The Commission recommends that the Congress update the composite rate by the projected rate of increase in the end-stage renal disease market basket index less 0.4 percent for calendar year 2006, to balance expectations for continued productivity gains with concerns about the trend in the Medicare margin and the uncertainty in payments due to recent changes in law and regulation.

Spending

- Because there is no provision in current law to change the composite rate in 2006, this recommendation will increase federal program spending relative to current law by between \$50 million and \$200 million for calendar year 2006 and less than \$1 billion over five years.

Beneficiary and provider

- This recommendation increases beneficiary cost sharing. No negative effects on beneficiaries' access to quality care are anticipated. This recommendation is not expected to affect providers' willingness and ability to provide quality care to Medicare beneficiaries. ■

Endnotes

- 1 To qualify for the ESRD program, individuals must be insured under the Social Security or Railroad Retirement program, be entitled to monthly benefits under the Social Security or Railroad Retirement program, or be the spouse or dependent child of an eligible beneficiary.
- 2 Medicare spending includes program outlays and beneficiary cost sharing.
- 3 The composite rate was designed in 1983 to include all nursing services, supplies, equipment, and selected drugs associated with a single dialysis session.
- 4 Before payment is case-mix adjusted, CMS will apply a budget-neutrality factor of 0.9116 to the wage-adjusted composite rate and add-on adjustment. The MMA requires that the case-mix adjusted payment system result in the same aggregate amount of expenditures for such services as would have been made in 2005, 2006, and 2007 if payments were not case-mix adjusted.
- 5 The body measurement variables are not used to calculate case-mix adjusted payments for patients under age 18.
- 6 The OIG is mandated to conduct two studies on the pricing of dialysis drugs. The first study, published in May 2004, examined the pricing of drugs with a billing code before 2004. The second study, due to the Congress by April 2006, will examine the pricing of drugs that did not have a billing code in 2004.
- 7 In the final rule, CMS indicated its plans to analyze the implications of recommending revisions to the current wage index before updating it (CMS 2004b).
- 8 The four largest for-profit chains are Fresenius, Gambro, DaVita, and Renal Care Group.
- 9 Medicare pays for more than 20 injectable drugs provided by freestanding dialysis providers. Each injectable drug has its own unit of measurement. Because of the difficulty in aggregating different units of measurement, we express volume in terms of total Medicare payments.
- 10 Levocarnitine supplements the loss of carnitine, a naturally occurring substance in the body that helps transport long-chain fatty acids for energy production. Patients on hemodialysis can suffer carnitine deficiencies from dialytic loss, reduced renal synthesis, and reduced dietary intake. Patients must show improvement from the levocarnitine treatment within six months for Medicare to continue to pay for the treatment.
- 11 The primary sponsor of the NKF guideline for the treatment of anemia is Amgen, the manufacturer of erythropoietin. Some providers contend that erythropoietin is predominately given intravenously because patients experience less discomfort than when it is given subcutaneously.
- 12 Daily parenteral nutrition is limited to patients “with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient’s general condition” (CMS 2004a).
- 13 For example, Dialysis Corporation of America (a regional chain) announced that it was establishing a new facility in Ohio, and National Renal Alliance (a regional chain) opened facilities in Louisiana, Alabama, and Tennessee.
- 14 CMS is proposing to implement a national policy that contractors will use when paying for erythropoietin. The proposed policy uses a combination of a patient’s hematocrit level and erythropoietin dosage amounts to trigger contractor review of the medical justification for the dosage. If the dosage is found not to be justified, payments are reduced to lower dosage levels.
- 15 We have not yet included laboratory payments in our analysis of current payments because of the difficulty in identifying dialysis-related tests from other tests ordered for comorbidities.
- 16 The National Kidney Foundation’s clinical guideline recommends use of vitamin D therapy to reduce the parathyroid hormone levels in hemodialysis and peritoneal dialysis patients meeting specific clinical criteria. The clinical guideline also recommends trials to compare the effectiveness of each of these agents among dialysis patients.
- 17 Audited 2001 cost reports refer to those obtained from CMS in September 2004; 11 percent of these cost reports were settled by an audit. Unaudited 2001 cost reports refer to those obtained from CMS in September 2003; only 1 percent of these cost reports were settled by an audit.

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